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Please find below and/or attached an Office communication concerning this application or proceeding.

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# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 01102009

Application Number: 09/556,143 Filing Date: April 17, 2002 Appellant(s): Schachar, Ronald

> William a. Munck For Appellant

**EXAMINER'S ANSWER** 

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This is in response to the appeal brief filed October 20, 2008.

# (1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

# (2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

11/322,728	Notice of Appeal filed September 2, 2008
11/323,752	Notice of Appeal filed September 2, 2008

## (3) Status of Claims

The statement of the status of claims contained in the brief is correct.

## (4) Status of Amendments After Final

No amendments after final have been filed.

#### (5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

#### (6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

## (7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

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# (8) Listing of Evidence Relied Upon

The following is a listing of the prior art of evidence (e.g. patents, publications Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

Number Name Date

(Title)

Safety of High-Energy March et al 1987

Neodymium:YAG Laser

Pulses in YAG Sclerostomy

# (9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 40-59 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by March et al.

March et al teach removing scleral tissue by irradiating it with a laser to treat glaucoma. Stedman's Medical Dictionary defines ablate as "to remove"; abrade as "to wear away by mechanical action"; and incise as "to cut with a knife" since the laser produces no mechanical action per se and is not a knife per se, abrade will be construed to indicate wearing away by action of the light and incise will be construed to indicate cutting by action of the light. Since the laser burns through the sclera at the treatment site, there must be some tissue interposed the margin of the treatment site and the boundary beyond which the scleral tissue is not affected by the treatment wherein the collagen fibers are partially decomposed.

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(10) Response to Argument

I) Claims 40-59 Are Properly Rejected Under 35 U.S.C. 102(b) As Being Clearly

Anticipated by March et al

Firstly appellant argues that the examiner must provide a basis in fact and/or technical

reasoning to reasonably support the determination that the inherent characteristic inherently

flows from the teachings of the applied art, citing MPEP 2112. Next appellant discusses the

teachings of March et al, noting that they pertain to creating a fistula or drainage channel

completely through the sclera of the eye. The purpose of this treatment is to lower intraocular

pressure by allowing the aqueous humor to drain. And appellant also asserts that this "new

technique is an improvement over previous laser treatments that failed to create a complete

scleral perforation" (internal quotes omitted, emphasis added), citing page 586, the right column

of March et al. However, the cited portion of March et al mentions nothing of "failure" to create

a fistula, the passage in question reads "a number of previous laser treatments for glaucoma have

been advanced and used clinically, none of these previous treatments created a complete scleral

perforation or sclerostomy" but does not in any way imply that the previous techniques were

intended to create a sclerostomy.

Turning to the claims, appellant notes the limitations of claim 40, which is herein

reproduced:

A method of operating a laser to treat one of presbyopia, hyperopia,

primary open angle glaucoma and ocular hypertension, said method comprising

the steps of:

Irradiating a sclera of an eye in a region of a ciliary body to thereby weaken the sclera sclera of the eye and thereby increase an effective working distance of a ciliary muscle of the eye;

Wherein irradiating the sclera comprises reducing a thickness of the sclera in the region of the ciliary body without forming an opening completely through the sclera.

Then appellant asserts that claim 40 requires that (i) the sclera is irradiated in a particular area to weakening the sclera and increase the effective working distance of the ciliary muscle and (ii) this is done without forming an opening completely through the sclera. Next appellant asserts that since the goal of March et al is to form a complete perforation of the d\sclera, March et al "cannot possibly anticipate claim 40".

The examiner must respectfully disagree. As appellant has chosen to file comprising-type (i.e. open ended) claims, these claims include processes which ultimately produce a full scleral perforation. Further, as already stated in the office action mailed June 29, 2007 (see page 2, the second full paragraph thereon), "The treatment of March after, for example the first 10 shots (i.e. prior to the endpoint of the treatment) reads on the instant claims" Thus these arguments are not convincing.

Continuing, appellant argues that the examiner "can rely on only two other teachings in *March* as anticipating claim 40:" (1) the previous laser treatments and (2) the time between pulses during the treatment taught by March et al.

With regard to (1), appellant argues that the examiner has not shown that the prior art discussed by March et al had the objective of increasing the effective working distance of the ciliary muscle. However, it is not required that the prior art set out to do what applicant is claiming to do. If all the steps of the method are performed, then any recited result must be produced, else the claim is incomplete as not reciting a critical step necessary to produce the claimed result. Next appellant argues that March et al never disclose the exact locations of the previous laser treatments. However, the originally filed disclosure provides no guidance as to

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the exact location of any laser application either, other than it be in the sclera. Thus the disclosure of March et al provides the irradiation location with all the specificity of the instant specification, and thus reads on the claims. Lastly appellant argues that there is no indication "that an adequate amount of tissue is removed to weaken the sclera". However, this issue has already been addressed repeatedly, most comprehensively in the office action mailed December 15, 2007, particularly in the paragraph bridging pages 3 and 4 thereof, which is repeated for appellant's convenience:

"Continuing, applicant asserts that the examiner has provided no fact or technical reasoning to support the determination of inherency. The examiner firstly notes, that the disclosures of the prior art are to be read in light of the knowledge of one of ordinary skill in the art. Given that one of ordinary skill in the art must at the very minimum be a ophthalmological surgeon, and therefore, have not only completed college with at least one course in physics and chemistry, but gone to a minimum of 3 years of medical school and interned for a period of time after that, one having ordinary skill must be recognized as being a highly educated surgeon. Given this level of education, the examiner respectfully submits that one of ordinary skill in the art would recognize that removing tissue from a structure such as the sclera must necessarily weaken the structure. The examiner is unaware of any process, material, or theory that affords or asserts the ability of strengthening a structure, or even allowing the structure to remain at the same strength, while removing some of the material that constitutes this structure. If applicant is aware of any such disclosure, the examiner would be most interested to review it. Absent any such showing, however, the examiner must rely upon the laws of physics as they are currently understood and presume that removal of the substance of a structure will leave that structure weaker than before the removal. Given that the structure is weaker, this necessarily requires that the structure will expand due to the internal pressure thereof in combination with it's weakened state. This expansion will also necessarily cause the effective working distance of the ciliary muscle to increase given that the ciliary muscle joins the iris to the sclera (see Figure 8-1 of Alders, cited above, since the sclera will expand due to the pressure in the eye pushing the now weakened (by the removal of tissue) sclera farther out. Thus the examiner must respectfully submit that one of ordinary skill in the art would immediately recognize that the intended results recited in the claim would, at least to a small degree, be produced by the procedure of March et al."

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Thus, since any removal of tissue will weaken the sclera to some degree, and thus cause it to expand to some degree, and thereby increase the working distance of the ciliary muscle to come degree, the claims are anticipated by prior art disclosed by March et al, as no particular degree of increase of the working distance is disclosed or claimed.

With regard to (2) appellant argues that the examiner "cannot possibly establish that for the brief period between the start of the laser treatment and the complete formation of the scleral perforation, March inherently anticipates irradiating a sclera of the eye...to thereby weaken the sclera of the eye and increase an working distance of a ciliary muscle of the eye. The Examiner has never even attempted to show that an adequate amount of tissue is removed during the new treatment of *March* to weaken the sclera or increase the ciliary muscle's effective working distance during this brief period of time" (internal quotes omitted). The examiner must respectfully disagree. As set forth above, even the minutest weakening of the sclera, producing a miniscule expansion thereof will produce some increase in the working distance of the ciliary muscle. Thus, as appellant has chosen not to recite any amount, degree, or extent to which the claimed working distance is increased, any increase, even a minute one for any amount of time, reads on the claimed invention. The examiner has encouraged appellant to bring to the attention any "process, material, or theory that affords or asserts the ability of strengthening a structure or even allowing the structure to remain at he same strength while removing some of the material that constitutes that structure" as set forth above, in the quoted text from the office action of December 15, 2006, but appellant has declined to do so. Thus, as the examiner has put forth a reasoned explanation based on scientific fact, and as appellant has chosen not to provide any

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evidence to the contrary, choosing instead to present only opinions without any explanation of an underlying rationale to support them, these arguments are not convincing.

With regard to the statement referring to changing pressure in the eye, the examiner was merely explaining that since pressure variations exist in the eye, for example due to blood pulsation therein, that the girth of the eye will vary along with these pressure variations, which in turn will vary the working distance of the ciliary muscle. As to the discussion in the office action of December 15, 2007, no law was created, but merely reported by the examiner. With respect to the remarks in the Advisory Action of June 25, 2008, the statement that "structures made of no material would be as strong or stronger as a structure which did contain material" is not a "strawman argument" it is in fact the logical extension of the position appellant has taken against the examiner's reasoned explanation of the consequences of the surgical method of March et al. As stated before, appellant has declined to provide any proof or evidentiary showing of the position taken with respect to the examiner's reasoned explanation, therefore, the examiner has illustrated the fallacy of such a position via *reductio ad absurdum*.

As the examiner has provided a reasoned explanation based on scientific principles and facts, the requirements of MPEP 2112 have been satisfied, and a showing of anticipation has been made. As appellant has failed to provide any sort of evidentiary showing or reasoned explanation as to why the examiner's reasoned explanation is incorrect or in error, the arguments are not convincing.

## (11) Related Proceedings Appendix

**NONE** 

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(12) Conclusion

It is the examiner's firm opinion that the appealed claims are not patentable for the

reasons argued above. Appellant has presented no convincing argument as to why the rejections

set forth above are not obvious or proper. Therefore, it is respectfully submitted that the final

rejection be affirmed.

Respectfully submitted,

/david shay/

Primary Examiner, Art Unit 3769

David Shay February 18, 2009

Conferees

/Henry M. Johnson, III/ Supervisory Patent Examiner, Art Unit 3769

/Greg Vidovich/ TQAS, TC 3700

David Shay

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